

**Notice of Allowability**

Application No.

10/070,764

Examiner

S. Devi, Ph.D.

Applicant(s)

CHADDOCK ET AL.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 10/19/06.
2. ☒ The allowed claim(s) ~~is/are~~ 41-45 and 47-51, now renumbered as claims 1-5 and 6-10 respectively, are allowed.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☒ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☒ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  5. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_\_
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_



## ATTACHMENT TO NOTICE OF ALLOWABILITY

### Applicants' Amendment

- 1) Acknowledgment is made of Applicants' after-final amendment filed 10/19/06 in response to the final Office Action mailed 06/19/06.

### Examiner's Amendment

- 2) An Examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to Applicants, an amendment may be filed as provided by 37 C.F.R. 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee. The authorization to prepare this Examiner's amendment was provided by Mr. Timothy Shea Jr. in a telephonic interview on 06 November 2006.

The instant application has been amended as indicated below:

- (a) Claims 41 and 47 have been amended as indicated below:

--Claim 41 (Currently amended). A method of removing residual clostridial neurotoxin from a preparation of ~~elestridial~~ LH<sub>N</sub> of clostridial neurotoxin comprising:

(i) applying a preparation comprising ~~elestridial~~ LH<sub>N</sub> of clostridial neurotoxin to a first affinity column, wherein said first affinity column comprises a first ligand immobilized on said first affinity column, and wherein said first ligand selectively binds to the residual clostridial neurotoxin but does not bind to the ~~elestridial~~ LH<sub>N</sub>, thereby forming an immobilized first ligand-clostridial neurotoxin complex, and an eluate comprising the ~~elestridial~~ LH<sub>N</sub>, wherein said eluate may contain an amount of the first ligand-clostridial neurotoxin complex that has become detached from the first affinity column;

(ii) contacting said eluate with a second affinity column, wherein said second affinity column comprises a second ligand immobilized on said second affinity column, and wherein said second ligand selectively binds to the first ligand-clostridial neurotoxin complex, if present in the eluate, but does not bind to the ~~elestridial~~ LH<sub>N</sub> present in the eluate; and thereby removing the residual clostridial neurotoxin from the preparation of the LH<sub>N</sub>--

--Claim 47 (Currently amended). A method of removing residual clostridial neurotoxin from a preparation of ~~elestridial~~ LH<sub>N</sub> of clostridial neurotoxin comprising:



(i) applying a preparation comprising ~~elestridial~~ LH<sub>N</sub> of clostridial neurotoxin to a first affinity column, wherein said first affinity column comprises a first ligand immobilized on said first affinity column, and wherein said first ligand selectively binds to the residual clostridial neurotoxin but does not bind to the ~~elestridial~~ LH<sub>N</sub>, thereby forming an immobilized first ligand-clostridial neurotoxin complex, and an eluate comprising the ~~elestridial~~ LH<sub>N</sub>, wherein said eluate may contain an amount of the first ligand-clostridial neurotoxin complex that has become detached from the first affinity column;

(ii) contacting said eluate with a second affinity column, wherein said second affinity column comprises a second ligand immobilized on said second affinity column, and wherein said second ligand selectively binds to the first ligand of the first ligand-clostridial neurotoxin complex, if present in the eluate, but does not bind to the ~~elestridial~~ LH<sub>N</sub> present in the eluate; and thereby removing the residual clostridial neurotoxin from the preparation of the LH<sub>N</sub>--

### **Status of Claims**

3) Claims 41 and 47 have been amended via the amendment filed 10/19/06.

Claim 46 has been canceled via the amendment filed 10/19/06.

New claims 48-51 have been added via the amendment filed 10/19/06.

Claims 41 and 47 have been amended via this Examiner's amendment.

Claims 41-45 and 47-51 are pending and are under examination.

### **Rejection(s) Moot**

4) The rejection of claim 46 made in paragraph 8 of the Office Action mailed 06/19/06 under 35 U.S.C. § 112, first paragraph, as containing new matter, is moot in light of Applicants' cancellation of the claim.

5) The rejection of claim 46 made in paragraphs 9(e), 9(f) and 9(g) of the Office Action mailed 06/19/06 under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claim.

### **Rejection(s) Withdrawn**

6) The rejection of claims 41-45 and 47 made in paragraph 8 of the Office Action mailed 06/19/06 under 35 U.S.C. § 112, first paragraph, as containing new matter, is withdrawn in light of



Applicants' amendment to the base claims.

7) The rejection of claim 41 made in paragraph 9(a) of the Office Action mailed 06/19/06 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

8) The rejection of claim 41 made in paragraphs 9(b), 9(c) and 9(d) of the Office Action mailed 06/19/06 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

9) The rejection of claim 47 made in paragraphs 9(e) and 9(h) of the Office Action mailed 06/19/06 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

10) The rejection of claims 42-45 made in paragraph 9(i) of the Office Action mailed 06/19/06 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the base claim.

### **Remarks**

11) Claims 41-45 and 47-51, now renumbered as claims 1-5 and 6-10 respectively, are allowed.

12) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Central Fax number (571) 273-8300, which receives facsimile transmissions 24 hours a day and 7 days a week.

13) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.Mov>. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

14) Any inquiry concerning this communication or earlier communication(s) from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail service. The Examiner can normally be reached on Monday to Friday from 7.15 a.m to 4.15 p.m. except one day each bi-week which would be disclosed on the



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Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Acting Supervisor, Bruce Campell, can be reached on (571) 272-0974.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

November, 2006



S. DEVI, PH.D.  
PRIMARY EXAMINER